

EXHIBIT 38

EXPERT REPORT
DAVID KESSLER, M.D.

PART A: QUALIFICATIONS AND SCOPE

I. QUALIFICATIONS

1. My name is David A. Kessler, M.D. I received my M.D. degree from Harvard Medical School in 1979 and my J.D. degree from the University of Chicago Law School in 1978.

2. I did my pediatrics training at Johns Hopkins Hospital.

3. I was appointed in 1990 by President George H. W. Bush as Commissioner of the United States Food and Drug Administration (“FDA”) and was confirmed by the United States Senate. I also served in that position under President William Jefferson Clinton until February 1997.

4. I have taught food and drug law at Columbia University Law School, and I have testified many times before the United States Congress on food, drug, and consumer protection issues under federal and state law. Over the last thirty years, I have published numerous articles in legal, medical, and scientific journals on the federal regulation of food, drugs, and medical devices. I have had special training in pharmacoepidemiology at Johns Hopkins Hospital. My resume, including a list of my published books and articles, is included in Appendix A. A list of cases in which I have appeared as a witness, and documentation of my expert witness fee, is attached as Appendix B.

5. As Commissioner, I had ultimate responsibility for implementing and enforcing the United States Food, Drug, and Cosmetic Act. I was responsible for overseeing five Centers within the FDA. They included, among others, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research. In addition to those duties, I placed high priority on getting promising therapies for serious and life-threatening diseases to patients as quickly as possible. During my tenure as Commissioner, the FDA announced a number of new programs including: the regulation of the

marketing and sale of tobacco products to children; nutrition labeling for food; user fees for drugs and biologics; preventive controls to improve food safety; measures to strengthen the nation's blood supply; and the MEDWatch program for reporting adverse events and product problems involving both drugs and devices. I created an Office of Criminal Investigation within the Agency to investigate suspected criminal violations of the Food, Drug, and Cosmetic Act, FDA regulations, and other related laws. I worked closely with and was ultimately responsible for the FDA's Division of Drug Marketing, Advertising and Communications. I have published articles on drug promotion and marketing practices.¹ I have likewise written extensively on the issue of addiction and have been heavily involved in the science of addiction since investigating and regulating nicotine-containing tobacco products while at FDA.

6. I am a senior advisor to TPG Capital, a leading global private equity firm, which owns pharmaceutical and biomedical companies. I previously served on the board of Aptalis Pharma and Tokai Pharmaceuticals, and I currently serve on the board of the medical device and biologics company Immucor, Inc. In these advisory and fiduciary capacities, I have advised companies on the standards and duties of care in the pharmaceutical and medical device industry. I also previously chaired the compliance committees of Aptalis, and I currently chair the quality committee of Immucor, which involves ensuring compliance with FDA laws and requirements.

7. Listed in Appendix C are documents I accessed independently from various sources, including but not limited to the FDA's website and the relevant discovery databases, and documents that have been provided to me by counsel. At my request, Appendix C was prepared

¹ These include: Kessler, D. (1990). The federal regulation of prescription drug advertising and promotion. JAMA 264:2409-15; Kessler, D. (1991). Drug promotion and scientific exchange. The role of the clinical investigator. N Engl J Med 325:201-3; Kessler, D. (1991). Communicating with patients about their medications. N Engl J Med 325:1650-2; Kessler, D. Therapeutic-class wars--drug promotion in a competitive marketplace. N Engl J Med 331:1350-3; Kessler, D. (2007). Direct-to-consumer advertising: is it too late to manage the risks? Ann Fam Med 5:4-5.

by counsel. Based on my review of those documents and my training and experience, I have a number of opinions that are detailed below.

8. The causes of action in this litigation include: public nuisance; negligence; common law fraud; civil conspiracy; violation of the Racketeer Influenced and Corrupt Organizations (“RICO”) Act; violation of consumer protection laws; and unjust enrichment.

9. It is my understanding that the plaintiffs include: County of Cuyahoga and County of Summit.

10. Likewise, it is my understanding that the defendants in this action are as follows: Actavis LLC, Actavis Pharma, Inc., Allergan Finance LLC, Allergan PLC, AmerisourceBergen Drug Corporation, ANDA, Inc., Cardinal Health, Inc., Cephalon, Inc., CVS Indiana, LLC, CVS Rx Services, Inc., Discount Drug Mart, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., H.D. Smith Holding Company, H.D. Smith Holding Company (County of Cuyahoga Only), H.D. Smith Holdings LLC, H.D. Smith Holdings, LLC (County of Cuyahoga Only), H.D. Smith LLC d/b/a H.D. Smith, H.D. Smith, LLC d/b/a H.D. Smith (County Of Cuyahoga Only), HBC Service Company, Health Mart Systems, Inc., Health Mart Systems, Inc. (County of Cuyahoga only), Henry Schein Medical Systems, Inc., Henry Schein Medical Systems, Inc. (County of Summit only), Henry Schein, Inc., Henry Schein, Inc. (County of Summit only), Insys Therapeutics, Inc., Janssen Pharmaceuticals, Inc., Johnson & Johnson, Mallinckrodt LLC, Mallinckrodt PLC, McKesson Corporation, Miami-Luken, Inc., Noramco, Inc., Par Pharmaceutical Companies, Inc., Par Pharmaceutical, Inc., Prescription Supply, Inc., Purdue Pharma, Inc., Purdue Pharma, L.P., Rite Aid of Maryland, Inc. d/b/a Rite-Aid Mid-Atlantic Customer Support Center, Inc., Specgx LLC, Teva Pharmaceutical Industries, Ltd., Teva

Pharmaceuticals USA, Inc., The Purdue Frederick Company, Inc., Walgreen Co., Walgreen Eastern Co., Walmart Inc., Watson Laboratories, Inc.

11. The opioid products discussed in this report include: OxyContin (Purdue), OxyContin Reformulated (Purdue), MS Contin (Purdue), Opana ER (Endo), Opana ER reformulated (Endo), Percocet (Endo), Duragesic (Janssen), Nucynta IR (Janssen), Nucynta ER (Janssen), Actiq (Teva), Fentora (Teva), Kadian (Actavis), Exalgo (Mallinckrodt), Xartemis ER (Mallinckrodt), and generic OxyContin (Mallinckrodt).

II. SCOPE

12. I have been asked by counsel for the plaintiffs to discuss drug sponsor obligations under standards provided under United States food and drug laws, regulations, guidances, and industry practice as they pertain to prescription opioids, and to discuss the purposes of those obligations and standards and the effect, if any, that any departures from those standards would be expected to have on the use, misuse and abuse of prescription opioids during the past two decades or so. I have also been asked to review the discovery records of specified defendant opioid manufacturers² for the purpose of formulating an opinion as to whether any one or more of those manufacturers departed from accepted drug regulatory standards and, if so, to describe how.³

² As used throughout this report, the term "manufacturer" refers to a sponsor of a drug.

³ The following Schedules are attached to this Report:

Schedule 1 contains general information about the drugs that are the subject of this Report.

Schedule 2 contains the approval dates of various dosages of the drugs that are the subject of this Report.

Schedule 3 contains a Morphine Milligram Equivalent (MME) conversion table.

Schedule 4 contains definitions of addiction and related terms.

Schedule 5 contains a list of Defendants and Plaintiffs in this MDL.

Schedule 6 contains relevant communications from FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC).

Schedule 7 contains relevant FDA Advisory Committee materials.

Schedule 8 contains IMS sales data for the drugs that are the subject of this Report. I understand from counsel that this Schedule has been prepared by Greylock McKinnon Associates.

Schedule 9 contains FDA's Risk Evaluation and Mitigation Strategies (REMS) requirements for oral opioids.

organizations, and were involved in varying ways in the development and dissemination of guidelines and other promotional materials published by these groups that served the common purpose of expanding the use of opioids.

578. Through these guidelines and other materials, the opioid manufacturers contributed to altering the standard of care for the treatment of pain by encouraging healthcare providers to view pain as a “fifth vital sign” that demanded aggressive treatment with opioids.

579. In addition, these guidelines and materials echoed certain statements made by the manufacturers regarding the risks and benefits of opioids that lacked substantial supporting evidence and were false and misleading.

580. As discussed below, the opioid manufacturers’ support for and involvement with pain advocacy, professional medical and trade group organizations, expanded the use of opioids and increased the risk of addiction abuse, overdose and death.

A. American Pain Society

581. According to its bylaws, the American Pain Society (“APS”) is a “multidisciplinary community that brings together a diverse group of professionals to increase the knowledge of pain and transform public policy and clinical practice.”¹¹⁵⁹

582. Since at least 1995, APS has received funding from several opioid manufacturers.

582.1. Between 1997 and 2012, Purdue paid the APS more than \$3,000,000.00.¹¹⁶⁰

582.2. Between 1997 and 2012, Janssen paid the APS more than \$1,700,000.00.¹¹⁶¹

¹¹⁵⁹ See <http://americanpainsociety.org/uploads/about/APS%20Bylaws%20revised%2001.21.2019.pdf>; JAN-MS-00409411.

¹¹⁶⁰ SFC00000001.

582.3. Between 1998 and 2012, Endo paid the APS \$4,468,253.10.¹¹⁶²

582.4. Between 2009 and 2013, the APS was paid \$278,000.00 by Covidien and \$218,000.00 by Teva.¹¹⁶³

583. APS has maintained a “Corporate Council” program that is sponsored by opioid manufacturers. Through this program, APS “connects” members of this “Corporate Council” to “multidisciplinary leaders in the science of pain.” Members of APS’s Corporate Council include Endo, Actavis, Mallinckrodt, Purdue, and Janssen.¹¹⁶⁴

584. In addition, APS has maintained an “APS Clinical Guidelines Program” funded by opioid manufacturers. In exchange for sponsorship, opioid manufacturers are permitted “to sit on the founding members’ guideline committee and provide input into topics for guideline development, as well as suggestions of clinicians for participation in the guidelines development process, methods of dissemination/adoption, etc.”¹¹⁶⁵ Members of APS’s Guidelines Program include Purdue, Endo, and Janssen.¹¹⁶⁶

585. As described below, APS has published newsbulletins and guidelines that were authored by individuals with direct ties to opioid manufacturers and which contained the same misleading statements regarding the benefits and risks of opioids as those used by opioid manufacturers in their branded promotion.

¹¹⁶¹ JJ-SFC-00000001.

¹¹⁶² ENDO-OR-CID-00754369 at 30.

¹¹⁶³ APS-MDL00000001.

¹¹⁶⁴ TEVA_MDL_A_00499668 at 24; *see also* U.S. Senate Homeland Security & Governmental Affairs Committee, Minority Staff Report (2018), *Fueling an Epidemic (Report Two) – Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* at 13.

¹¹⁶⁵ ENDO-OPIOID_MDL-06234663.

¹¹⁶⁶ PKY181215749 at 14; PKY181775488.

1. APS/AAPM Guideline – The Use of Opioids for the Treatment of Chronic Pain

586. In 1997, in a joint publication with the American Academy of Pain Medicine (“AAPM”), APS and AAPM published a guideline titled “The Use of Opioids for the Treatment of Chronic Pain,”¹¹⁶⁷ containing the following misleading statements regarding opioids:

586.1. “Studies indicate that the de novo development of addiction when opioids are used for the relief of pain is low.”¹¹⁶⁸

586.2. “[E]xperience has shown that known addicts can benefit from the carefully supervised, judicious use of opioids for the treatment of pain due to cancer, surgery, or recurrent painful illnesses[.]”¹¹⁶⁹

586.3. “It is now accepted by practitioners of the specialty of pain medicine that respiratory depression induced by opioids tends to be a short-lived phenomenon, generally occurs only in the opioid-naïve patient, and is antagonized by pain. Therefore, withholding the appropriate use of opioids from a patient who is experiencing pain on the basis of respiratory concerns is unwarranted.”¹¹⁷⁰

586.4. “Furthermore, for most opioids, there does not appear to be an arbitrary upper dosage limit, as was previously thought.”¹¹⁷¹

586.5. “The undertreatment of pain in today’s society is not justified. This joint consensus statement has been produced pursuant to the missions of both organizations, to

¹¹⁶⁷ PPLPC051000030818 at 2.

¹¹⁶⁸ PPLPC051000030818 at 2.

¹¹⁶⁹ PPLPC051000030818 at 2.

¹¹⁷⁰ PPLPC051000030818 at 2.

¹¹⁷¹ PPLPC051000030818 at 2.

help foster a practice environment in which opioids may be used appropriately to reduce needless suffering from pain.”¹¹⁷²

587. The authors of this guideline included those with ties to opioid manufacturers, including: J. David Haddox, M.D.,¹¹⁷³ David Joranson,¹¹⁷⁴ Richard Payne, M.D.,¹¹⁷⁵ and Richard Portenoy, M.D.¹¹⁷⁶

588. In the same year that this APS guideline was published, the following manufacturers made the following payments to APS:

588.1. For example, in 1997, Purdue reportedly paid \$48,501 and Janssen paid \$146,245 to the APS.¹¹⁷⁷

588.2. Likewise, Purdue paid \$36,800 and Janssen paid \$43,500 to the AAPM in 1997.¹¹⁷⁸

589. This guideline was used by opioid manufacturers in promoting their opioid products and opioids in general.¹¹⁷⁹

¹¹⁷² PPLPC051000030818 at 4.

¹¹⁷³ At the time, Dr. Haddox was a paid speaker for Purdue. *See, e.g.*, PKY180955294 at 1. He was subsequently employed by Purdue as the Vice President of Risk Management and Policy. J. David Haddox Depo. Tr. 57:7-18.

¹¹⁷⁴ Mr. Joranson is the former director of the University of Wisconsin Pain & Policy Study Group, which was funded by the opioid manufacturers. ENDO-OPIOID_MDL-00658641 at 2-3. The Pain and Policy Study Group also received payments from the manufacturers. *See, e.g.* ENDO-OR-CID-00754369 at 30, SFC00000001.

¹¹⁷⁵ At the time, Dr. Payne was a paid speaker for Purdue. *See, e.g.*, PKY180256893 at 1, PKY180256892 at 1, PKY180783690 at 1.

¹¹⁷⁶ At the time, Dr. Portenoy was a paid speaker for Purdue. *See, e.g.*, PKY180357269 at 1.

¹¹⁷⁷ 2012.06.08 Purdue Summary of Payments by Name and Year SFC00000001; J&J Janssen SFC 2012 Submission JAN00000001.

¹¹⁷⁸ 2012.06.08 Purdue Summary of Payments by Name and Year SFC00000001; J&J Janssen SFC 2012 Submission JAN00000001.

¹¹⁷⁹ *See, e.g.*, PKY181199494 at 17, 25; PKY181137481 at 8; ALLERGAN_MDL_02158487 at 1; ABT-MDL-KY-0009437 at 54; ENDO-OPIOID_MDL-05967764 at 1.

2. APS/AAPM/ASAM – Definitions Related to the Use of Opioids for the Treatment of Pain

590. In 2001, APS developed consensus “Definitions Related to the Use of Opioids for the Treatment of Pain” in coordination with AAPM and the American Society of Addiction Medicine (“ASAM”), containing the following misleading statement concerning pseudoaddiction: “An individual's behaviors that may suggest addiction sometimes are simply a reflection of unrelieved pain or other problems unrelated to addiction.”¹¹⁸⁰

591. In the same year that this 2001 APS/AAPM/ASAM guideline was published, the following manufacturers made the following payments to APS/AAPM/ASAM:

591.1. For example, in 2001, Purdue reportedly paid \$211,211, Janssen paid approximately \$159,000, and Endo paid \$132,400 to APS.¹¹⁸¹

591.2. Likewise, Purdue paid \$80,273, Janssen paid \$66,764, and Endo paid \$22,000 to AAPM in 2001.¹¹⁸²

591.3. That same year, Endo paid \$10,000 to ASAM.¹¹⁸³

592. It appears that Endo may have influenced the final product,¹¹⁸⁴ and that Purdue was heavily involved in the development of these definitions. Dr. Haddox noted, “Purdue has been at the forefront of efforts to promote the proper therapeutic use of opioid analgesics, including funding the very first meeting of the AAPM/APS/ASAM

¹¹⁸⁰ PDD1502210202 at 254.

¹¹⁸¹ See SFC00000001; END00000002; JAN00000001.

¹¹⁸² END00000002; JAN00000001.

¹¹⁸³ ENDO-OPIOID_MDL-06234588; JAN00000001.

¹¹⁸⁴ See END00211516.

leadership (when I was president of AAPM) to begin the collaboration that eventually led to the Consensus statement on definitions of pain and addiction.”¹¹⁸⁵

593. This guideline was used by opioid manufacturers in promoting their opioid products and opioids in general.¹¹⁸⁶

3. APS Arthritis Guidelines

594. In 2002, the APS issued “Guidelines for the Management of Arthritis Pain,” containing the following misleading statements:

594.1. “The prevalence of addiction among patients with pain who do not have a previously existing substance abuse disorder is low.”¹¹⁸⁷

594.2. “Weissman and Haddox (1989) noted that patients who are given doses of opioids that are inadequate to relieve their pain or whose opioid dose is discontinued abruptly or tapered too rapidly may develop characteristics that resemble addiction, which they termed iatrogenic ‘pseudoaddiction.’”¹¹⁸⁸

594.3. “Tolerance to analgesia is uncommon once pain relief has been achieved and there is no progression of disease.”¹¹⁸⁹

594.4. “Opioids should be used for patients with OA and RA when other medications and nonpharmacologic interventions produce inadequate pain relief and the patient's quality of life is affected by the pain.”¹¹⁹⁰

¹¹⁸⁵ PPLP003477086 at 24.

¹¹⁸⁶ See, e.g., END00212229; ENDO-OPIOID MDL-01997737; ENDO-OPIOID_MDL-02939611 at 68; END00212229; ABT-MDL-KY-0009437 at 54.

¹¹⁸⁷ PKY181215749 at 95.

¹¹⁸⁸ PKY181215749 at 95.

¹¹⁸⁹ PKY181215749 at 96.

¹¹⁹⁰ PKY181215749 at 97.

594.5. “Extensive experience and evidence in the management of chronic malignant pain supports the use of long-acting opioids to improve patient adherence, minimize medication level peaks and valleys, and minimize side effects. These advantages also appear to apply to the use of long-acting opioids in the management of arthritis pain, but the cost-effectiveness of the advantages has not been shown.”¹¹⁹¹

594.6. “The limited study data on effective doses of opioids for OA pain demonstrate efficacy at relatively low doses. Both immediate release and controlled release forms have been effective.”¹¹⁹²

595. The authors of this guideline included several with ties to opioid manufacturers, including Arthur G. Lipman, M.D.,¹¹⁹³ Margaret Caudill-Slosberg, M.D.,¹¹⁹⁴ and April Hazard Vallerand, Ph.D., R.N.¹¹⁹⁵

596. Opioid manufacturers funded the “APS Guidelines Program,” which the APS used to fund its consultants.”¹¹⁹⁶

597. This guideline was used by opioid manufacturers in promoting their opioid products and opioids in general.¹¹⁹⁷

¹¹⁹¹ PKY181215749 at 98.

¹¹⁹² PKY181215749 at 102. When Purdue had concerns about the content of APS materials, it reached out to KOLS involved in the development of the materials to confirm a favorable result for Purdue. For example, when Purdue’s Sally Riddle voiced her worries about the content of the APS Arthritis Guidelines, she communicated these to Harry Lazarus, who then spoke with the chair of the Guidelines, Art Lipman. After speaking with Dr. Lipman, Harry reported back to Sally “I don’t think you will be disappointed with the guidelines.” PPLPC009000006145; *see also* E513_00090393.

¹¹⁹³ Dr. Lipman was a consultant and paid speaker for Endo and Purdue. *See* PKY181215749 at 15.

¹¹⁹⁴ Dr. Caudill-Slosberg was a paid speaker for Purdue. *See* PKY181215749 at 15.

¹¹⁹⁵ Dr. Vallerand was a paid speaker for Purdue and Janssen. *See* PKY181215749 at 15.

¹¹⁹⁶ PKY181215749 at 15.

¹¹⁹⁷ *See, e.g.*, PPLPC012000051510 at 8, PPLPC012000051508, E01_00013311 at 2, PPLP003281201, PPLP012000063578; *see also* APS-MDL00000061 at APS-MDL00000062 (APS Arthritis Guidelines Total Distribution between 2002 and 2007: 193,308); PKY181947933 at 2.

B. American Academy of Pain Medicine

598. According to the mission statement of the American Academy of Pain Medicine (“AAPM”), its purpose is to “provide for quality care to patients suffering with pain, through education and training of physicians, and through the advancement of specialty of Pain Medicine.”¹¹⁹⁸

599. The AAPM received millions of dollars in funding from opioid manufacturers.

599.1. Between 1997 and 2012, Purdue provided more than \$2,000,000.00 in funding to the AAPM,¹¹⁹⁹ and from 2012 and 2017, AAPM received an additional \$700,000.00 from Purdue.¹²⁰⁰

599.2. Between 1997 and 2011, Janssen provided more than \$560,000.00. in funding to the AAP,¹²⁰¹ and from 2012 to 2017, Janssen funded the AAPM with an additional \$83,000.00.¹²⁰²

599.3. From 2010 to 2016, Mallinckrodt provided at least \$239,000.00 in funding to the AAPM.¹²⁰³

¹¹⁹⁸ JAN-MS-00723779.

¹¹⁹⁹ SFC00000001.

¹²⁰⁰ Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups. U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member’s Office, PPLPC031001561047 at 5. Also available at <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf>.

¹²⁰¹ JJ-SFC-00000001.

¹²⁰² Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups. U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member’s Office, PPLPC031001561047 at 5. Also available at <https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf>.

¹²⁰³ CHI_000441993 at 18.

600. As noted in the section above pertaining to the American Pain Society (“APS”), AAPM and APS issued a joint guideline in 1997 that contained misleading statements regarding the safety of opioids.¹²⁰⁴

601. In addition to these guidelines, AAPM provided continuing medical education that was coordinated, at least in part, by opioid manufacturers such as Purdue. For example, an April 2000 email from Purdue’s Robin Hogen described Purdue’s relationship with Dr. Barry Cole, who would later become AAPM’s Executive Director:

[Dr.] Barry [Cole] is now on the road five days a week for Purdue – and seems very happy. He believes he can be more helpful to the Company by remaining a third party – unencumbered by FDA guidelines for what he can say about our products or the class of drugs. By flying under the umbrella of American Academy of Pain Management, he has tremendous credibility and cannot be discounted as a company flak.¹²⁰⁵

602. Similarly, in a May 2001 email exchange involving the AAPM’s Dr. Cole and Purdue’s Dr. Reder, Dr. Cole offered to “provide a written statement for Purdue’s support” and

¹²⁰⁴ AAPM also made misleading statements concerning the risk of addiction in other promotional materials. For example, in a 2005 Question and Answer session with the president of the American Academy of Pain Medicine, Dr. Scott Fishman gave the following misleading statements:

We know that the risks of addiction are there, but they are small and can be managed.many have argued that if we try in our zeal to minimize the risk to avoid drugs that are addictive, we often wind up using drugs that may be even more toxic, such as NSAIDs or potentially, in some patients, COX-2 inhibitors.

PPLPC0128341 at 3. Likewise, in a 2011 “Interactive Exploration of Integrated Opioid Therapy in Chronic Pain” presentation by AAPM, the following misleading statements were made:

Some long-acting opioids help maintain steady blood serum blood levels, help patients sleep through the night, and eliminate the need for frequent dosing” and that “the less frequent administration may discourage binge behavior in patients with risks for misuse.

MNK-T1_0000984477 at 16.

¹²⁰⁵ PDD8801104393. *See also* PPLPC029000042442 at 2. In this May 2001 email, Dr. Barry Cole wrote the following to Purdue’s Dr. Reder:

Dr. Reder, Thought you’d like to see these items before next weeks meetings in CT.[...] I am attaching some articles and letters from the Cleveland Free Times....all very supportive of OxyContin and calling into question what may be entirely manufactured news. I have spoken with the reporter 3 times. He has asking all of the right questions about the OxyContin “scare.”

Id.

noted that he was “happy to prepare something as an individual or in some official capacity with the American Academy of Pain Management” for the “FDA Advisory Committee meeting in Maryland on June 14/15,” since in Dr. Cole’s opinion “this is all just ‘too much about nothing.’”¹²⁰⁶

C. American Pain Foundation

603. Founded in 1997, the American Pain Foundation (“APF”) described itself as “the nation’s leading independent nonprofit organization serving people with pain.”

604. APF ceased operating in 2012 following congressional questioning about its ties to the pharmaceutical industry, including opioid manufacturers.

605. APF received millions of dollars in funding from opioid manufacturers.

605.1. Between 1999 and 2012, Purdue provided more than \$3,600,000.00 in funding to APF.¹²⁰⁷

605.2. Mallinckrodt contributed a total of \$97,000 in funding to the APF.¹²⁰⁸

605.3. Between 1997 and 2012, Janssen funded APF with more than \$600,000.00.¹²⁰⁹

605.4. Between 1999 and 2012, Endo provided at least \$5,941,671.40 in funding to the APF.¹²¹⁰

¹²⁰⁶ PPLPC029000042442 at 1.

¹²⁰⁷ SFC00000001; *see also* 2001 APF Highlights.((CHI_000406606 at 55) (noting Purdue as its largest funder and also identifying Abbott, Anesta, Bristol-Myers Squibb, Cephalon, Janssen, Knoll, Ligand, McNeil Consumer, Medtronic, Novartis, Ortho-Biotech, Pharmacia, Pfizer, Roxane and Warner Lambert at part of their “broad corporate support.”)

¹²⁰⁸ MNK-T1_0008005740.

¹²⁰⁹ JJ-SFC-00000001.

¹²¹⁰ END00041232 at 8.

606. In exchange for funding APF, opioid manufacturers expected and received inclusion in APF decision making.

606.1. For example, in an August 5, 2000 email from Purdue's Robin Hogen to Dr. David Haddox concerning funding to APF, Hogen stated, "[i]f they want our bucks (and they honestly cannot survive without industry support) they are going to have to learn to live with 'industry' reps on their board. I don't think they can expect huge grants without some say in governance."¹²¹¹

606.2. By at least 2001, APF's Board included members with ties to opioid manufacturers, including Dr. Richard Campbell, a paid consultant for Purdue,¹²¹² and Dr. Richard Portenoy, a paid consultant and speaker for Purdue and Janssen.¹²¹³

607. APF has published promotional materials that contained the same misleading statements regarding the benefits and risks of opioids as those used by opioid manufacturers in their branded promotion.

607.1. In 2000, APF published a "Pain Action Guide" that contained the misleading claim that addiction is rare:

Pain medications rarely cause addiction. Morphine and similar pain medications, called opioids, can be highly effective for certain conditions. Unless you have a history of substance abuse, there is little risk of addiction when these medications are properly prescribed by a doctor and taken as directed. Physical dependence - which is not addiction - may occur as a result of taking these medications if you stop taking these medications suddenly. This usually is not a problem if you go off your medications generally.¹²¹⁴

¹²¹¹ PPLPC025000012558.

¹²¹² PPLP003477687.

¹²¹³ See PKY180772092; ENDO-OPIOID_MDL-01610298; PPLPC020000005715; PDD8801291781; PKY182717470; JAN-MS-00312347.

¹²¹⁴ ABT-MDL-KY-0025968; TEVA_MDL_A_05356629.

607.2. In April 2001, APF issued a news release titled “Balancing News Stories About Opioids,” which again misleadingly claimed addiction to be rare, and further claimed without substantial evidence that opioid medications rarely produce a “high” and allow patients to return to normal lives:

Taking legal, FDA-approved opioid medications as prescribed, under the direction of a physician for pain relief, is safe and effective, and only in rare cases, leads to addiction. When properly used, these medications rarely give a ‘high’ – they give relief. And, most importantly, they allow many people to resume their normal lives.¹²¹⁵

607.3. In 2007, APF provided “messages” to be used in training patient advocates regarding the use of opioids, including the statement that “[p]ain is a national healthcare crises. It is our Nation’s hidden epidemic.” These “messages” also included the following misleading statement regarding addiction:

The public—including doctors and people with pain – often believe that opioid medications are addictive and produce euphoria. The fact is that when properly prescribed by a healthcare professional and taken as directed, these medications give relief – not a ‘high.’¹²¹⁶

607.4. In October 2007, Endo sponsored an APF event “focusing on the vital need for better pain care for members of the military and veterans” entitled “Freedom From Pain: It’s Your Right.”¹²¹⁷ Endo’s financial support for the event included the preparation of a “fact sheet.”¹²¹⁸ The fact sheet included the following statements that downplayed the risk of addiction:

“A number of concerns and misconceptions stand in the way of optimal pain management. These may include fears about”

¹²¹⁵ PKY180302903 at 107.

¹²¹⁶ PPLP004046286 at 2.

¹²¹⁷ ENDO-OPIOID_MDL-02807915 at 3; CHI_000430399.

¹²¹⁸ *Id.* at 2.

“Becoming ‘drugged up’ or addicted to pain medications, if they are prescribed;”¹²¹⁹

*“Unless someone has a past or current history of substance abuse, the chance of addiction is very low when these medications are prescribed by a doctor and taken as directed.”*¹²²⁰

607.5. APF made a similarly misleading statement regarding addiction in the 2009 book titled Exit Wounds – A Survival Guide to Pain Management for Returning Veterans and their Families: “[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medication.”¹²²¹

607.6. Likewise, in 2011, APF made the following statement regarding addiction in its “Policymaker’s Guide to Understanding Pain & Its Management”:

Under a section titled “some common misconceptions about pain” it was stated that “use of strong pain medication leads to addiction. Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive. As with any medication, there are risks, but these risks can be managed when these medicines are properly prescribed and taken as directed.”¹²²²

608. In addition to promoting the misleading claim that opioids are rarely addictive, APF responded to negative media attention related to diversion and abuse of opioids.

608.1. An internal APF presentation highlighted the “Media Frenzy over OxyContin and Other Opioids” and “How APF Has Been Fighting Back.”¹²²³ The presentation highlighted the fact that the APF was involved in “educating the media” by

¹²¹⁹ ENDO-OPIOID_MDL-02807915 at 7.

¹²²⁰ *Id.* at 8.

¹²²¹ SFC00005694 at 107.

¹²²² ENDO-OPIOD_MDL-00654219 at 7.

¹²²³ CHI_000406606 at 42.

“handl[ing] over 125 calls and inquiries from national, state-wide and local media” and “educated journalist on value of opioids while dispelling myths and misconceptions.”¹²²⁴ Further, the APF stated that it had “testified before congress and FDA” and had been “vocal in new pain forum with DEA” where they “insisted on major changes to DEA’s ‘consensus statement.’”¹²²⁵ APF further stated that it “educated professionals” with presentations with titles such as “are pain patients becoming collateral damage in the war on drugs” and “recent federal actions on opioids.”¹²²⁶

608.2. Similarly, the 2001 APF Board of Director Meeting Minutes state that:

[A]s a result of a NY Times article on OxyContin abuse suggesting a link between APF and Purdue Pharma, APF developed a proactive approach to the rise in reports on the negative effects of OxyContin. APF’s media response to queries is that “opioids are one of the most effective ways to treat pain. They offer pain relief, not a ‘high’, when prescribed by a doctor and taken as directed. Opioid-related deaths are the result of ‘drug abuse.’”¹²²⁷

D. Federation of State Medical Boards

609. According to its website, the Federation of State Medical Boards (“FSMB”) is a national non-profit organization representing all 70 state medical and osteopathic boards within the United States and its territories that license and discipline allopathic and osteopathic physicians and, in some jurisdictions, other health care professionals.”¹²²⁸

610. The FSMB received funding from opioid manufacturers.

¹²²⁴ *Id.* at 43.

¹²²⁵ *Id.* at 45.

¹²²⁶ *Id.* at 48.

¹²²⁷ CHI_001260895 at 6.

¹²²⁸ <http://www.fsmb.org/about-fsmb> (last visited Mar. 22, 2019).